

Exhibit F



March 23, 2006

Food and Drug Administration
 Center for Devices and Radiological Health
 Medical Device Reporting
 Attn: Jenne Liu, RN, MSN
 P.O. Box 3002
 Rockville, Maryland 20847-3002

RE: Manufacturer Report Number: 2020394-2006-00018

Dear Ms Liu:

Bard Peripheral Vascular, Inc. (BPV), a division of C.R. Bard, Inc. received your request for additional information, dated February 7, 2006, concerning Manufacturer's MedWatch Report Number, 2020394-2006-00018. Please note that a follow-up MedWatch report with the device evaluation and information from the Information for Use was submitted on February 25, 2006. In an effort to provide clarification and ease of review, the FDA question/comment is noted in bold italics and is followed by BPV's response.

1. Any evaluation of the incident described in the medical device report by the attending physician, surgeon, hospital representative or the health care professional.

The following information was received from the physician and was evaluated during the investigation. The patient was male in his 20's admitted with multiple injuries after a motor vehicle accident. Injuries included cervical spine and thoracic spine fractures and quadriplegia.

05	Date of Admission
Redacted 05	Left subclavian vein line placed
05	T3-T4 laminectomy and fusion of C-spine fracture
05	IVC filter placement via right femoral vein. Cava Diameter 24mm.
05	Subclavian line removed
Redacted 05	Tracheostomy
05	Gastrostomy tube placement.
Redacted 05	Follow up cavagram and CT showed filter has moved caudally 1 vertebral body from time of placement. No intraluminal thrombus in IVC. Alignment of filter with IVC ok. 3 struts appeared to be penetrating caval wall. Patient was asymptomatic.
Redacted 05	Filter retrieval

1625 West 3rd Street • P.O. Box 1740 • Tempe, AZ 85280-1740
 Tel: 1-800-321-4254 • 1-480-894-9515 • Fax: 1-480-966-7062 • www.bardpv.com



An outside medical consultant for BPV reviewed the patient's clinical history, the X-Rays and CT scans. The placement of the gastrostomy tube and vigorous pulmonary toilet procedures performed on this quadriplegic patient may have contributed to this event.

2. A copy of all current labeling for the device, including directions for use, caution statements, technical manuals and product performance reports.

Please see attached copy of the Information for Use for the G2 Filter System, Femoral.

3. A more complete description of investigation, evaluation, failure analysis and/or laboratory testing, including data on specific components involved, as applicable, methodology (ies) used for analysis and/or testing, and follow-up efforts taken to date. Please include a copy of any investigation, evaluation, failure analysis, and/or laboratory testing summary relevant to the reported event.

As stated in the follow-up MedWatch Report, all measurements taken on the returned filter confirmed that the filter met specifications. No defects were seen on the filter.

4. State the expected and observed frequency and severity of occurrence for the reported incident with this device.

As defined in the Design Failure Modes and Effects Analysis (DFMEA) for this product, the original expected frequency of occurrence was less than or equal to 0.05% (1 in 2000). The observed frequency of occurrence for this severity level is 0.067% (6 in 8942), as of February 28th, 2006. As the actual rate of occurrence exceeds the expected rate, the level of risk for this specific failure mode was reassessed in the DFMEA. Upon secondary assessment, the overall risk level, which consists of occurrence, severity, and detection, remains below the risk threshold. The risk remains at an acceptable level.

If you have any questions regarding this response, please do not hesitate to contact Cynthia Walcott by telephone at (480) 303-2747 or by fax at (480) 303-2774.

Kind Regards,

Cynthia Walcott RN
Cynthia Walcott, RN
Senior Manager, Clinical Assurance

1625 West 3rd Street • P. O. Box 1740 • Tempe, AZ 85280-1740
Tel: 1-800-321-4254 • 1-480-894-9515 • Fax: 1-480-966-7062 • www.bardpv.com